FEB 2 4 2012

510(k) Summary
for
Sony LMD-2451MT LCD Monitor
(per 21 CFR 807.92)

1. APPLICANT / SPONSOR

Sony Electronics Inc.
Sony Medical Systems Division
1 Sony Drive
Park Ridge, NJ 07656

Contact Person: Ms. Aleta Moeller
Telephone: 201-358-4182

Date Prepared: February 9, 2012

2. DEVICE NAME

Proprietary Name: Sony LMD-2451MT LCD Monitor
Common/Usual Name: Monitor
Classification Name: Endoscope and Accessories

3. PREDICATE DEVICE

- Polarized 3D Monitor XOEV-3D1, Olympus Medical Systems Corporation, K102379

4. DEVICE DESCRIPTION

The Sony LMD-2451MT LCD Monitor is intended primarily for use in a medical environment for displaying images captured during minimally invasive surgical procedures. The monitor features a 24-inch widescreen LCD display panel and employs full WUXGA high-definition (HD) performance.

The LMD-2451MT also features Sony's ChromaTru® technology for accurate and consistent color matching across multiple monitors. The monitor is 2D/3D switchable and, therefore, is compatible with both 2D and 3D camera systems to show color and texture variations in full HD in both 2D and 3D modes. In addition to digital signals, the LMD-2451MT accepts analog signals and converts them to digital signals.

The 3D mode of the Sony LMD-2451MT LCD Monitor enables more realistic depth perception and spatial orientation than is available in the 2D mode. A micro-polarizer 3D filter is built into the monitor and lightweight circular polarizer 3D glasses are supplied as accessories.

The Sony LMD-2451MT LCD Monitor is designed with the flexibility to support a variety of formats with two built-in option slots to select, expand, and change input/output signals.

5. INTENDED USE

The Sony LMD-2451MT LCD Monitor is intended to provide 3D and 2D color video displays of images from surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The LMD-2451MT is a widescreen, high-definition, medical grade monitor for real-time use during minimally invasive surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sony LMD-2451MT LCD Monitor has the same overall purpose and function as the predicate device cited above. Both of the devices are intended to provide color video displays of images from surgical camera systems, primarily in endoscopic/laparoscopic applications.

7. PERFORMANCE TESTING

Testing of the Sony LMD-2451MT LCD Monitor demonstrated that the device is in compliance with applicable requirements of recognized standards for electromagnetic compatibility and electrical safety.

8. CONCLUSION

Based on the similarities in overall purpose and function, the Sony LMD-2451MT LCD Monitor has demonstrated substantial equivalence to the cited predicate device and any differences do not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 4 2012

Sony Electronics, Inc.
% Medical Device Consultants, Inc.
Ms. Cynthia Sinclair
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K113203
Trade/Device Name: Sony LMD-2451MT LCD Monitor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 09, 2012
Received: February 10, 2012

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Sony LMD-2451MT LCD Monitor

Indications for Use: K113203

The Sony LMD-2451MT LCD Monitor is intended to provide 3D and 2D color video displays of images from surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The LMD-2451MT is a widescreen, high-definition, medical grade monitor for real-time use during minimally invasive surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113203